This document is scheduled to be published in the Federal Register on 05/25/2018 and available online at https://federalregister.gov/d/2018-11256, and on FDsys.gov

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Amy Petrik, 240-627-3721;

amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application

listed below may be obtained by communicating with the indicated licensing contact at

the Technology Transfer and Intellectual Property Office, National Institute of Allergy

and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A

signed Confidential Disclosure Agreement will be required to receive copies of

unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

1

ANTIBODIES AND METHODS FOR THE DIAGNOSIS AND TREATMENT OF EPSTEIN-BARR VIRUS INFECTION

Description of Technology:

According to the World Health Organization, over 90% of the worldwide population is infected with Epstein-Barr virus by adulthood. In most cases, the disease accompanying initial infection is subclinical though some individuals who are infected as adolescents or adults do experience infectious mononucleosis. However, once infected, individuals carry latent EBV for their remaining lifespan. In such individuals, immune suppression can result in reactivation of the EBV and consequently, EBV-associated lymphoproliferative disease. Currently, there is no prophylactic to prevent primary EBV infection and additional therapeutics would be useful to treat EBV-associated B-cell driven lymphoproliferative disease.

Scientists at the NIAID are developing neutralizing antibodies, originally isolated from humans or non-human primates, that could be useful in preventing primary infection or reactivation of EBV in immunocompromised individuals. These antibodies are 10-100 times more potent than the most potent EBV neutralizing antibody identified to date (72A1). The antibodies target epitopes on either the gp350 surface glycoprotein of EBV or the gH/gL heterodimer. In vitro experiments have demonstrated that the antibodies effectively inhibit EBV infection of B cells and epithelial cells as well as cell-to-cell fusion of cells expressing the viral proteins gH/gL.

Potential Commercial Applications:

 Treatment of individuals with compromised immune systems to prevent EBVassociated lymphoproliferative diseases Prevention of primary EBV infection in individuals with compromised immune systems to prevent EBV-associated lymphoproliferative diseases

Competitive Advantages:

No EBV therapeutics or prophylactics currently exist

Development Stage:

• In vitro

Inventors: Masaru Kanekiyo (NIAID), W. Gordon Joyce (WRAIR), Wei Bu (NIAID), Jeffrey Cohen (NIAID)

Publications: N/A

Intellectual Property: HHS Reference Number E-001-2017 includes U.S. Provisional Patent Application No. 62/490,023 filed April 25, 2017 (Pending); PCT Application No. PCT/US2018/29463 filed April 25, 2018.

HHS Reference Number E-079-2018 includes U.S. Provisional Patent Application No. 62/665,977 filed May 2, 2018.

Related Intellectual Property: HHS Reference Number E-001-2017; E-079-2018

Licensing Contact: Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious

Diseases is seeking statements of capability or interest from parties interested in

collaborative research to further develop, evaluate or commercialize Epstein-Barr

monoclonal antibody technologies. For collaboration opportunities, please contact Dr.

Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

Dated: May 10, 2018

Suzanne M. Frisbie

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

[FR Doc. 2018-11256 Filed: 5/24/2018 8:45 am; Publication Date: 5/25/2018]